

FORM PTO-1390 (Modified)
(REV 10-95)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

251.00040101

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

09/1146323

INTERNATIONAL APPLICATION NO.

PCT/EP98/03764 ✓

INTERNATIONAL FILING DATE

19 June 1998 ✓

PRIORITY DATE CLAIMED

20 June 1997 ✓

TITLE OF INVENTION

DEVICE FOR TAKING AND EXAMINING SAMPLES ✓

APPLICANT(S) FOR DO/EO/US

SANNER, Stefan ✓

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 18 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
A **SECOND** or **SUBSEQUENT** preliminary amendment.
16. ☐ A substitute specification.
17. ☐ A change of power of attorney and/or address letter.
18. ☒ Certificate of Mailing by Express Mail
19. ☐ Other items or information:

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.445(a)(2))		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
09/446323		PCT/EP98/03764		258.00040101	
20. The following fees are submitted:				CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :					
<input type="checkbox"/> Search Report has been prepared by the EPO or JPO \$840.00					
<input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) \$670.00					
<input type="checkbox"/> No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) \$760.00					
<input checked="" type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$970.00					
<input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) \$96.00					
ENTER APPROPRIATE BASIC FEE AMOUNT =					
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)). <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30				\$970.00	
				\$130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	12 - 20 =	0	x \$18.00	\$0.00	
Independent claims	2 - 3 =	0	x \$78.00	\$0.00	
Multiple Dependent Claims (check if applicable).			<input type="checkbox"/>	\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$1,100.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). <input type="checkbox"/>				\$0.00	
SUBTOTAL =				\$1,100.00	
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)). <input type="checkbox"/> 20 <input type="checkbox"/> 30 +				\$0.00	
TOTAL NATIONAL FEE =				\$1,100.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input type="checkbox"/>				\$0.00	
TOTAL FEES ENCLOSED =				\$1,100.00	
				Amount to be: refunded	\$
				charged	\$
<input type="checkbox"/> A check in the amount of _____ to cover the above fees is enclosed.					
<input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
<input type="checkbox"/> The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. _____ A duplicate copy of this sheet is enclosed.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO:					
RAASCH, Kevin W. Mueting, Raasch & Gebhardt, P.A. P.O. Box 581415 Minneapolis, Minnesota 55458-1415 United States of America			SIGNATURE Kevin W. Raasch NAME 35,651 REGISTRATION NUMBER 20 December 1999 DATE		



13 Rec'd PCT/PTO 20 MAR 2000

09/44632

PATENT
Docket No. 258.00040101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Stefan Sanner)	Group Art Unit:	Unknown
Serial No.:	Unassigned)	Examiner:	Unknown
Filed:	Herewith)		
For:	DEVICE FOR TAKING AND EXAMINING SAMPLES			

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Attn: Box PCT
Washington, D.C. 20231

Dear Sir:

The present application is U.S. National Stage Application of International Application No. PCT/EP98/03764, filed 19 June 1998.

Prior to taking up the above-identified application for examination, please amend the application as follows:

In the Claims

Please amend the claims as follows:

At line 1 of claim 2, please delete "or 2".

At line 1 of claim 3, delete "or 2".

At line 1 of claim 5, delete "or 4".

At line 1 of claim 7, delete "to 6".

At line 1 of claim 8, delete "to 7".

At line 1 of claim 9, delete "or 8".

At line 1 of claim 10, delete "to 9".

At line 1 of claim 11, delete "to 10".

Preliminary Amendment

Serial No. Unassigned

Filed: Herewith

DEVICE FOR TAKING AND EXAMINING SAMPLES

Page 2 of 2

Conclusion

Prior to taking this application up for examination, the Examiner is asked to enter the above amendment. If the Examiner has any questions or concerns with respect to the present application, the Examiner is encouraged to contact the applicant's representative, Kevin Raasch, at (612) 305-1218. It is respectfully requested that the application be moved forward to allowance.

Respectfully submitted,
Stefan Sanner
By his representatives,
Muetting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
(612)305-1220

20 DECEMBER 1999
Date

By:

KWR
Kevin W. Raasch
Reg. No. 35,651
Direct Dial (612)305-1218

"Express Mail" mailing label number EL351920068US

Date of Deposit December 20, 1999

I hereby certify that this paper and/or fee is/are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Attn: Box PCT, Washington, D. C. 20231.

Jill R. Price
Name: Jill R. Price



Docket No. 258.00040101

SMALL BUSINESS
VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. §§1.90 AND 1.27(b)) - SMALL BUSINESS CONCERN

I hereby declare that I am

- a) () the owner of the small business concern identified below:
- b) () an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: Conner
ADDRESS OF CONCERN: Gesellschaft zur Optimierung von Forschung
und Entwicklung mbH
Am Klopffeld 19
D-52152 Mönchengladbach, GERMANY

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 C.F.R. §121.3-18, and reproduced in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Sections 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

- a) ☐ the specification filed herewith.
b) ☒ application serial no. Unassigned, filed December 20, 1999 (PCT/EP98/03764).
c) ☐ patent no. _____, issued _____.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern, or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor(s), who could not qualify as an independent inventor(s) under 37 C.F.R. §1.9(c) or by any concern that would not qualify as a small business concern under 37 C.F.R. §1.9(d) or a nonprofit organization under 37 C.F.R. §1.9(e). *NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention averring to their status as small entities. (37 C.F.R. §1.27)

NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME _____
ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. §1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME Christian Reider
TITLE Dr.
ADDRESS Gesellschaft zur Optimierung von Forschung und Entwicklung mbH, Am Klonfernsitz 19, D-82152 Martinsried, GERMANY
SIGNATURE Christian Reider DATE February 10, 2000

420 Rec'd PCT/PTO 20 DEC 1999

Device for Taking and Examining Samples

The present invention relates to a device for taking and examining samples, in particular for the integrated taking of samples and examination by means of test methods, in particular immunological, chemical or biochemical kinds of tests.

DE-C2-41 17 635 describes a multi-purpose examination device for fecal samples. This device comprises a housing with a cavity and a laterally arranged tube. A fecal sample is taken up by means of a stirring portion and introduced into the cavity, and this cavity is closed by means of a cap. An inner connection of the tube is wetted with the fecal sample. By means of a syringe, a highly sensitive reagent such as o-toluidine or tetramethyl benzhydriene and hydrogen peroxide is introduced into the cavity. Due to a color reaction it is tested whether the taken fecal sample contains traces of blood. For a further test, a slightly sensitive test reagent such as guaiac resin or lignum vitae resin and hydrogen peroxide are introduced through an opening at the free end of the tube. By observing a corresponding color reaction it is examined whether the fecal sample contains traces of blood. This examination device has a complicated design comprising a plurality of individual parts, and use thereof is difficult.

EP-A2-0 327 144 describes a sample taking container and a method for processing a pasty sample material. A sample taking cup for taking a sample and introducing it into the sample-taking container is arranged at the cover of a container by means of a shaft. A liquid for suspending the fecal sample is contained in the sample-taking container. After introducing the sample cup and subsequently screwing on the container cover, the fecal sample disperses in the liquid. After transportation into a laboratory, the container cover is removed and a second liquid, in particular an organic solvent (ether or ethyl acetate) or colorant (e.g. Lugol's solution) is added. For the subsequent filtration, a separate filter body is screwed on, and by shaking the filtered suspension is obtained in the filtrate container. The filtered suspension can then be examined. This device comprises a plurality of individual parts, and use thereof is difficult. In particular, there is a danger that the liquid is spilled during use of the device.

US-A-4 978 504 describes a test unit for taking and analyzing samples. The test unit comprises a holder, and at one end of a small rod a taking sponge is arranged by means of which a sample can be taken. The holder comprises a cavity in which a destroyable ampulla containing a reaction fluid is provided. After taking a sample, the small rod is introduced into a tube-shaped housing, and the holding means is attached. Then, the ampulla is destroyed by impressing the holding means and the reaction fluid flows into the housing and comes in contact with the sample. Then the mixture is collected in a container or dropped onto a carrier and examined by means of separate devices.

EP-A-0 520 408 describes a device which is suitable in particular for examining saliva samples. This test unit includes a cylindrical container containing a liquid and a sample collector shaped as a piston with a sponge arranged thereto for taking a saliva sample. After taking a sample, the sample collector is introduced into the housing and the sample collector sponge comes in contact with the liquid. The test device also comprises a collection container which can be attached to the other end of the housing and is displaceable with respect to the housing. In the interior of the collection container a thorn is arranged opposite of an opening at the other end of the housing, which opening is closed by a foil or sheet. In the attached position of the collection container, the foil or sheet is destroyed by the thorn and thus the opening is free. By introducing the piston-shaped sample collector completely, the liquid is pressed from the container into the collection container, and at the same time the sponge-like sample collector is pressed out. The collection container contains a reaction substance which reacts with the sample and the liquid, wherein this liquid is subsequently examined by means of a separate device. US-A-5 393 496 describes a similar test device.

It is an object of the present invention to provide a device for taking and examining samples which is designed in a simple manner and can be handled easily.

This object is achieved with the features of the claims. It is a particular advantage of the device of the present invention that the samples can be taken easily, that the sample-taking means containing the sample can be safely introduced into a housing and can be mixed therein in a simple manner with a sample reprocessing liquid and that then the sample can be examined by means of a testing means arranged in the housing.

A further advantage of the device according to the invention is that a sample reprocessing liquid is safely sealed in the cartridge and that the user does not come in contact with the sample also after mixing.

In the following, the invention is explained in more detail on the basis of an embodiment and by referring to the drawings in which

- Fig. 1 is a basic sketch of the construction of a device according to the invention,
- Fig. 2 a partial view of an embodiment of a sample-taking means according to the invention seen from the handle,
- Fig. 3 a partial view of the sample-taking means according to Fig. 2 seen from the sample,
- Fig. 4 a basic sketch of the device according to the invention, and
- Fig. 5 an enlarged perspective partial view of the device according to Fig. 4.

The device of Fig. 1 comprises a sample-taking means 10, a cartridge 30, a testing means 40 and a housing 50. As is indicated by the dashed lines, first the cartridge 30 is introduced into the tube-shaped housing 50 and subsequently the sample-taking means 10 is introduced into the housing 50 from the same side. A testing means 40 is introduced at the opposite side of the housing 50. Preferably, the cartridge 30 and/or the testing means 40 is displaceable within the housing 50 and secured against falling out.

Preferably, the device is constructed in the above-described manner and provided to a user for taking a sample and examination thereof. This arrangement represents a test kit which can be used in a simple manner and can also be handled by laypersons, in particular elderly people.

As shown in Fig. 2, the sample-taking means 10 consists of two half-tubes 11, 12 which form a tube (cylindrical cavity) when they are closed. The two half-tubes are connected with each other at one end (handle-facing end) by means of an elastic web 13 the stress of which presses the two halves apart so that they form a "V" when they are unstressed. In an alternative embodiment, the two half-tubes can be connected by a joint, wherein preferably the joint connection comprises a film hinge. For example, the film hinge can be arranged in a web connection between the half-tubes. Preferably, the web connection is shaped similar to the web 13 in

Fig. 2 and the film hinge is arranged in the area of the pointed end. In this embodiment both half-tubes can be freely pivoted with respect to each other. If a spring action is desired, additional spring means can be provided. At the inner surface of the one half-tube 11 a triangular oblong recess 14 is arranged which can be engaged with a corresponding counter groove 15 formed at the other half-tube 12. The recess 14 and the counter groove 15 form a guide which prevents the two half-tubes from moving out in the lateral direction when the sample-taking means is closed. At the handle-facing end of the outer surface of the half-tubes, a handling surface is provided with nubs 16 which prevent gliding-off during use. The handling surface is closed at the sample-facing side by a funnel-shaped, peripheral edge 17 which helps to avoid a contact with surplus sample material. At the sample-facing side of the peripheral edge 17 a steep thread 18 is formed at the outer surface of the tube consisting of the two half-tubes.

As shown in Fig. 3, at the sample-facing end of the sample-taking means 10 a first disk 21 is arranged at the one half-tube 12 and, spaced therefrom, a second disk 22. When closing the sample-taking means, i.e. when the two half-tubes 11, 12 contact each other, said two disks form a sample chamber 20. From the distance a between the two disks and the radius r of the half-tubes, the sample volume V to be taken is calculated as follows: $V = \pi \cdot r^2 \cdot a$. The length of the half-tubes 11, 12 is dimensioned such that between the handle-facing disk 22 and the above-described guide 14, 15 there is a sufficient space for optionally surplus sample material.

The sample-facing end disk 21 is connected to the inner surface of the half-tube 11 such that the connection resists to the forces caused during sample-taking; however, the disk 21 is broken out during introduction into the housing at one or a plurality of predetermined breaking points 23 by a resistance caused in the housing. A cone-shaped ring 24, the function of which is explained in more detail below, is attached to the outer edge of said disk 21. An indentation 25 is formed in the center of the disk 21. The area formed by this indentation corresponds to an opening of a truncated cone at the cartridge. Outside the indentation 25 the disk 21 has openings, so that a sieve 26 for mechanically opening the sample is realized. Instead of the indentation 25 a web, which will be described in more detail below, can be provided.

The handle-facing disk 22 is rigidly attached so that it resists to all forces caused during sample-taking and sample-processing.

With further reference to Fig. 4, the cartridge 30 is at first described in more detail. The cartridge 30 contains a liquid which is used, for example, for diluting and chemically opening the sample. The size of the interior space of the cartridge 30 and the amount of liquid M are selected such that the cartridge can take up the sample volume V in addition to the liquid already contained in the cartridge. The liquid amount M is provided in an exactly dosed relationship with respect to the given sample volume. The cartridge is shaped like a cylinder. At the edge facing the sample-taking means, the cylinder tapers so as to form a truncated cone 31; thus, the sieve 26 of the sample-taking means comprising the cone-shaped ring 24 centers itself on the cartridge. This cone-shaped seat preferably serves at the same time as a seal between the sample-taking means and the cartridge. At the end of the truncated cone of the cartridge, a circular impression 36 having an opening 32 in its center is formed. The opening is closed by a metal ball 33 arranged therein. The metal ball 33 is arranged in the opening for example by shrinking it on. In this case, the size of the metal ball 33 is slightly larger than the opening 32 at the cone-shaped end so that the ball can be pressed into the cartridge 30 when introducing the sample-taking means into the housing. Either the indentation 25 or a web arranged on the sieve is used for pressing the ball 33 in. A web is particularly advantageous if the ball is arranged in the cover surface of the cartridge in a recessed manner. The dimensions are selected such that preferably the cone surfaces are in a sealing contact as soon as the ball has been pressed completely into the cartridge.

The opposite end of the cylindrical cartridge 30 is closed by a bottom 34 in the center of which there is an impression 35 which is also cylindrical and projects into the cartridge 30. Said impression 35 serves for taking up the testing means 40. The impression and the testing means are realized such that the wall of the impression 35 can be broken, and thus the content of the cartridge can be brought in contact with a test strip contained in the testing means.

The testing means 40 has the shape of a cylinder and its cartridge-facing end tapers so as to form a truncated cone 41. At the tip of the truncated cone there is an opening 42 through which sample solution can enter. An absorbent material is introduced into the truncated cone, said absorbent material transporting the

sample fluid to the test strip (not shown) by capillary forces. The cylindrical testing means 40 comprises one or a plurality of recesses so that color reactions of the test strip can be observed as a result of the test. The closing material is preferably a porous, water-repellent material which prevents the sample fluid from penetrating the testing means but which, however, allows the air displaced by the sample fluid to escape.

The housing 50 serves for receiving, protecting and coordinating the above-described three components, i.e. the sample-taking means 10, the cartridge 30 and the testing means 40. It consists of a tube, the interior of which is divided into different diameters and the front portion of which has a thread 53. In the present embodiment, the front end serving as the introduction opening is funnel-shaped, has a high edge and preferably a considerably larger diameter than the sample-facing end of the sample-taking means. The frontal end 51 of the housing contacts the funnel-shaped, peripheral edge 17 and closes the introduction opening. Thus, a stripping chamber 52 is formed in which surplus sample material contained on the outer surface of the sample-facing end of the sample-taking means is stripped off and disposed. Following the stripping chamber 52, the diameter of the tube decreases so that the sample-facing end of the sample-taking means remains closed and can be displaced until it engages with a thread 53 at the inner surface of this portion. At the other part of the housing a sample-taking space 54 is provided which is adapted to the size and shape of the testing device 40 such that the tubular testing means 40 is held in it but can be moved back and forth when a slight pressure is applied. The center portion 55 contains the cartridge 30 which is held only by the testing means and hangs freely in any other respect and which can be displaced together with the testing means 40.

By means of the above-described device, a test is carried out as follows.

The test arrangement is mounted as follows. The sample-taking means 10 is removably inserted in the housing 50. The testing means 40 and the cartridge 30 are fitted into each other. The combination of the two is fixed in the rear part of the housing 50. The user removes the sample-taking means from the housing 50. If the connection between the half-tubes comprises an elastic web 13, the sample-taking means opens automatically. If a joint is provided, e.g. a film hinge, the user moves the half-tubes apart. The two half-tubes 11 and 12 form a "V". In the area of the sample chamber 20, the sample substance is now held and fixed. By

pressing the half-tubes together, the front edge of the sieve 26 mounted on the front end penetrates the sample and is held by the second half-tube on the opposite side. During the process of pressing the half-tubes together, the triangular projection 14 and the counter groove 15 engage with each other, a shearing action is prevented, and the two half-tubes 11, 12 close in a form-fit manner to form a complete tube. The sample substance is contained in the sample chamber 20. The sample chamber contains an exactly defined amount, optional surplus sample material is contained in the rear part of the sample-taking means, i.e. the surplus chamber. The sample-taking means is now introduced into the housing and centered to the middle by the funnel-shaped end portion of the stripping chamber 52. The sample-taking means is introduced until the external thread 18 contacts the internal thread 53. The semi-spherical indentation 25 of the front sieve 26 now contacts the closure ball 33 of the cartridge 30. The sample-taking means is now screwed into the housing; thus, the cartridge 30, which is held by the testing means 40 and pushed by the sieve 26, moves backwards (cf. Fig. 5). The tapering portion 56 for the testing means serves as a stopper for the cartridge, and the cartridge is fixed there. By this process, the testing means is also moved backwards and projects from the rear end of the housing. The fact that the combination cartridge/testing means is moved outwards to the back until it is actually fixed, prevents an early, undesired activation of the test strip. During the further turning movement, the closing ball 33 is pressed into the cartridge 30 by the sieve 26. The sieve 26 is then fixed on the cartridge 30 by the now meshing cone. By the arising pressure onto the sieve 26, the predetermined breaking point 23 is broken, the free sieve 26 is pressed onto the cartridge 30 by the sample. Then the sample is pressed into the cartridge 30 by the counter-pressure of the separating wall 22 between sample chamber and surplus chamber through the sieve 26, the space formed by the impression 36, and the opening 32.

After termination of this process, the sample is contained in the cartridge 30 which is closed by the sieve 26 leaning on it and the separating wall 22 pressing against it.

In order to finally mix the sample, which has already been slightly stirred by the sieve 26, with the liquid contained in the cartridge 30, the entire testing apparatus is now shaken. The closing ball 33 located in the interior of the cartridge 30 is now used as a mixing ball, which also becomes acoustically noticeable by a rattling noise. When the noise level decreases, the user can assume that the sample has

sufficiently mixed with the liquid and slows down the ball due to its higher viscosity.

The next step consists of activating the testing means projecting from the rear end of the housing. It functions as with a ball pen by quickly pressing the end of the testing means. During this process the membrane in the rear surface of the cartridge 30 is penetrated by the cone-shaped end 41 of the testing means. The liquid in the cartridge 30 passes through the hole 42 in the cone tip 41 into the interior of the testing means. A nonwoven arranged therein absorbs the liquid until it is saturated. A test strip arranged on this nonwoven is activated by the liquid and can subsequently be evaluated. The test result can be seen through a window or through a transparent design of the end of the testing means. In the scope of the invention, testing means can be used in which other ways of bringing the test strip (or the test substance) into contact with the sample mixture can be realized. As an alternative to the above-described embodiment, the cartridge can for example be realized such that it does not have an impression in the area of the bottom. In this case, an opening in the bottom is provided with a destroyable foil or sheet. After the foil or sheet has been destroyed, the sample mixture is forwarded to the test strip which optionally indicates a reaction. The above-mentioned foil or sheet is preferably an aluminum sheet or a multi-layer composite material which preferably comprises aluminum and plastics layers.

Preferably, the three components which the user can see, i.e. the sample-taking means, the housing and the testing means, are characterized by different colors. The components of the device according to the invention are preferably put to the user's disposal as a kit. For example, the mentioned components can be provided in one pack, e.g. a blister pack, separately from each other and ready for use.

In the meaning of the invention

- a) "variable coloring" means both different coloring and the variably strong coloring of the corresponding individual component by means of a selected individual color, and
- b) kit means a pack for producing a ready-to-use device for taking and examining samples.

It is an advantage of the device according to the invention that layperson can use it safely. In particular, penetration of sample material and the liquid contained in the cartridge, which can be toxic or caustic, is reliably avoided.

Moreover, the variable coloring supports the fact that the components are put together in the correct order.

In addition, a hygienic usability is ensured. Due to the integrated taking, processing and application of the sample, a defined relationship of sample amount and reagent amount is ensured.

Preferably, the components are produced from a plastic material which is suitable for the respective purpose. ABS is the material preferably used. In this case, the components are preferably produced by injection molding.

The described embodiments show only examples for the realization of the invention. The person skilled in the art can carry out constructional and functional modifications of the embodiments.

Claims

1. A device for taking and examining samples, comprising a housing (50) in which a cartridge (30), a testing means (40) and a sample-taking means (10) are positioned, wherein the cartridge (30) is displaceable within the housing (50) in such a manner that a sample introduced by means of the sample-taking means (10) can be mixed with a content of the cartridge (30) and wherein the testing means (40) is displaceable within the housing (50) in such a manner that the testing means (40) can be brought in contact with the sample mixture for analyzing the sample mixture.
2. The device according to claim 1, wherein the sample-taking means (10) can be introduced into an open end of the housing (50) and preferably comprises a steep thread (18) which cooperates with a corresponding internal thread (53) in the housing (50).
3. The device according to claim 1 or 2, wherein the sample-facing end of the sample-taking means (10) comprises a sample chamber (20).
4. The device according to claim 3, wherein the sample-taking means (10) consists of two half-tubes (11, 12) which are connected with each other preferably at the handle-facing end by means of a joint, preferably a film hinge, or an elastic web (13).
5. The device according to claim 3 or 4, wherein at least one of the two half-tubes (11, 12) comprises at its sample-facing end a first and a second disk (21, 22) limiting the sample chamber (20).
6. The device according to claim 5, wherein the sample-facing disk (21) comprises a sieve (26), an indentation (25) is preferably formed in the disk and preferably at the edge a cone-shaped ring (24) is attached, wherein the disk is connected to the sample-taking means (10) preferably by predetermined breaking points (23).
7. The device according to any one of claims 1 to 6, wherein one end of the cartridge (30) comprises an opening (32) which can be closed by means of a ball (33).

8. The device according to any one of claims 1 to 7, wherein the cartridge (30) has a bottom (34) which can be perforated.
9. The device according to claim 7 or 8, wherein the cartridge (30) is shaped cylindrically and comprises on one end a truncated cone (31) which can be engaged with the cone-shaped ring (24) on the sieve (26) of the sample-taking means (10), wherein the ball (33) contacts the indentation (25).
10. The device according to any one of claim 1 to 9, wherein the testing means has the shape of a cylinder whose cartridge-facing end tapers in the form of a truncated cone (41) and the tip thereof has preferably an opening (42).
11. The device according to any one of claims 1 to 10, wherein the testing means (40) can be brought in contact with the content of the cartridge (30) if the sample-taking means (10) is arranged in the housing.
12. A kit for preparing a ready-to-use device for taking and examining samples comprising
 - (a) a sample-taking means (10) for taking a sample,
 - (b) a housing (50) with a cartridge (30) arranged therein, and
 - (c) a testing means (40),
 wherein the sample-taking means (10) and the testing means (40) are introducible into the housing (50) and the testing means (40) can additionally be displaced after having been introduced into the housing (50).

Abstract**Device for Taking and Examining Samples**

The invention relates to a device for taking and examining samples, comprising a tube-shaped housing (50) in which a cartridge (30), a testing means (40) and a sample-taking means (10) are positioned, wherein a sample introduced by means of the sample-taking means (10) can be mixed with a content of the cartridge (30), and the testing means (40) is used to analyze the sample mixture.

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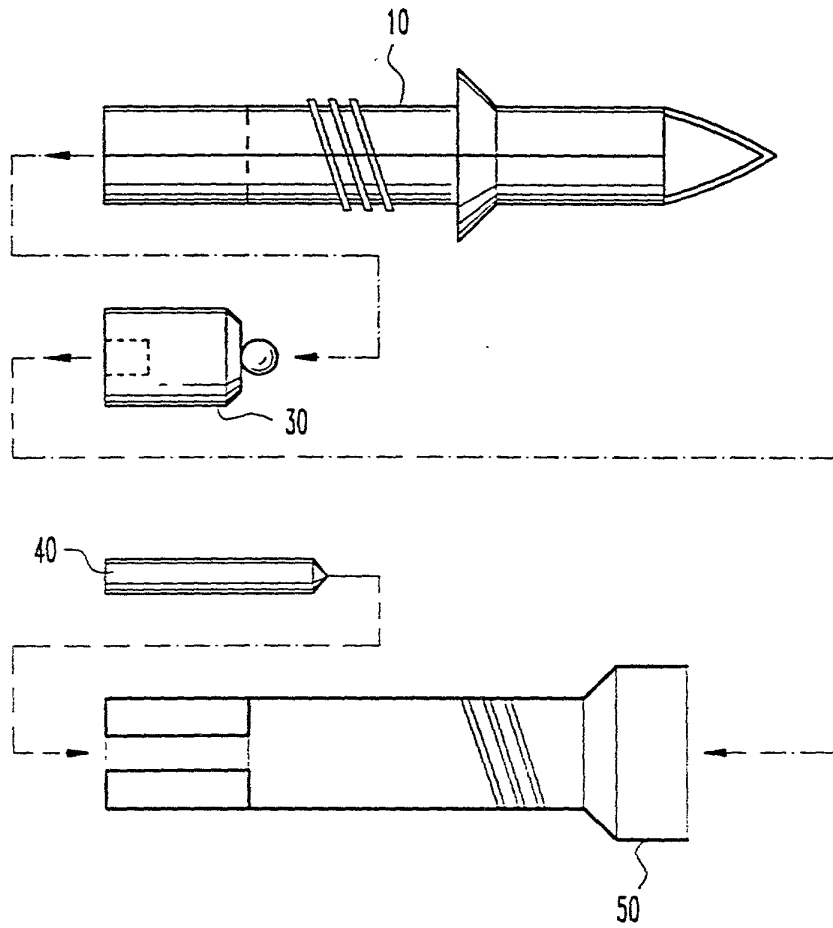


Fig.1

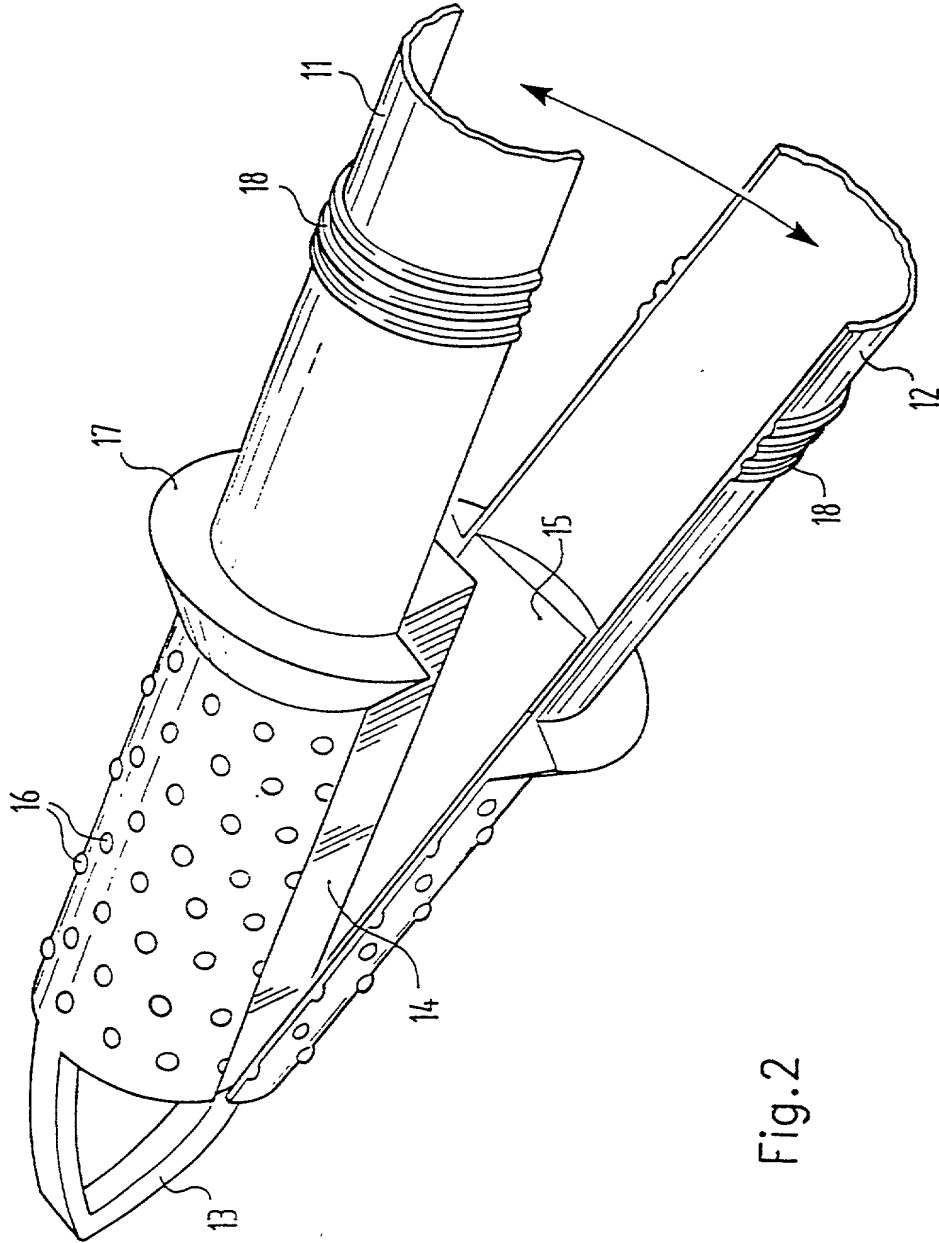


Fig. 2

Fig.3

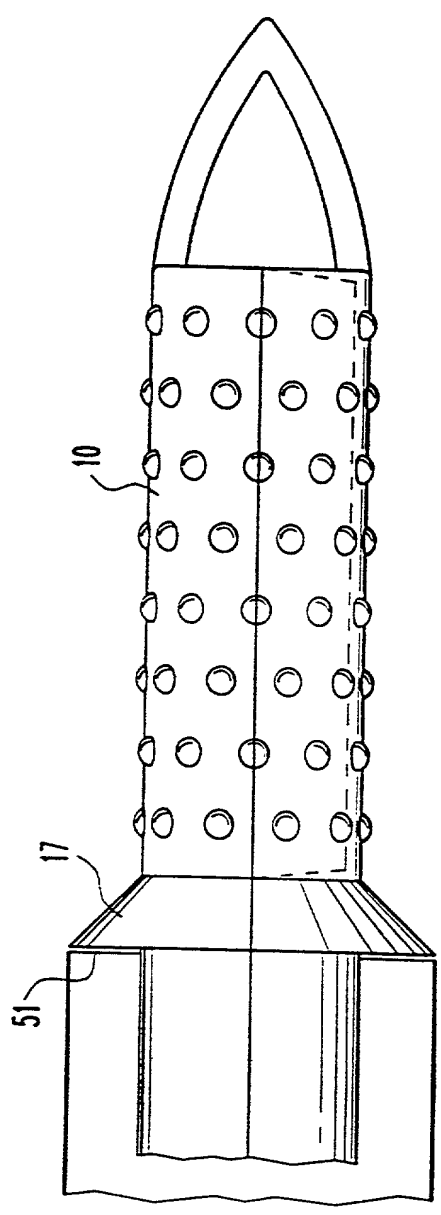
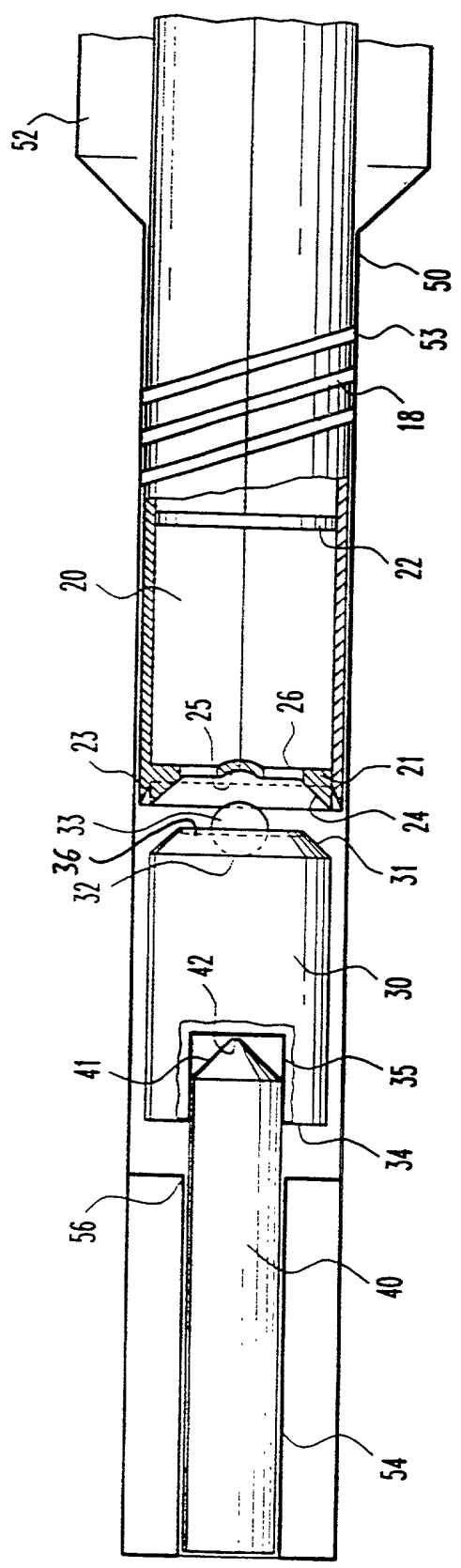


Fig.4

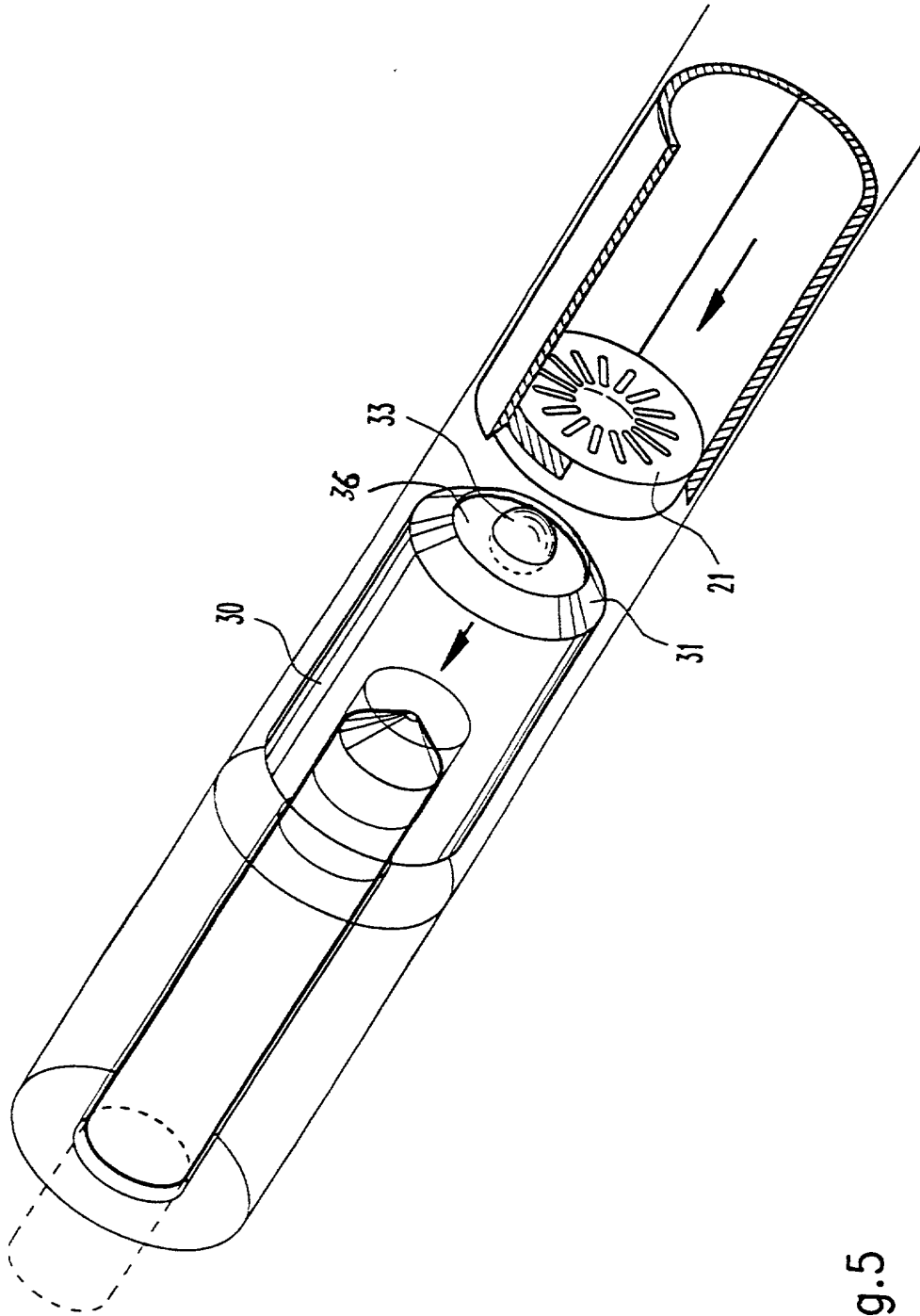


Fig. 5



CB1905

Docket No: 258.00040101

DECLARATION AND POWER OF ATTORNEY

I, Stefan Sanner, the sole inventor of the invention claimed, declare that: (1) my citizenship and mailing address are indicated below; (2) I have reviewed and understand the contents of the specification identified below, including the claims, as amended by any amendment specifically referred to herein, (3) I believe that I am the original and first inventor of the subject matter in

DEVICE FOR TAKING AND EXAMINING SAMPLES

Filed: December 20, 1999

Serial No.: Unassigned

described and claimed therein and for which a patent is sought; and (4) I hereby acknowledge my duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to the patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate listed below, or §365(a) of any PCT international application which designates at least one country other than the United States of America listed below, and have also identified below any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on the basis of which priority is claimed:

a. ☐ no such applications have been filed.b. ☒ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC §119(a)-(d), §365(a), and/or §365(b)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
DE	197 26 268.6	20 June 1997 (20.06.97)	

ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
NONE			

* Title 37, Code of Federal Regulations, §1.56 is reproduced on the attached page.

Declaration and Power of Attorney

Page 2 of 4

Serial No. Unassigned

Filing Date: December 20, 1999

Title: **DEVICE FOR TAKING AND EXAMINING SAMPLES**

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

- a. ☒ no such applications have been filed.
b. ☐ such applications have been filed as follows:

PROVISIONAL APPLICATION(S), IF ANY, UNDER 35 USC §119(e)	
APPLICATION NUMBER	DATE OF FILING (day, month, year)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States applications or §365(e) of any PCT international application(s) designating the United States of America, listed below. Insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

- a. ☐ no such applications have been filed.
b. ☒ such applications have been filed as follows:

US PARENT NUMBER	PCT PARENT NUMBER (day, month, year)	PARENT FILING DATE	STATUS (patented, pending, abandoned)
N/A	PCT/EP98/03764	19 June 1998 ✓ (19.06.1998)	

8 - I hereby appoint Ann M. Mueing (Reg. No. 33,977), Kevin W. Raasch (Reg. No. 35,651), Mark J. Gebhardt (Reg. No. 35,518), Mark A. Hollingsworth (Reg. No. 38,491), Victoria A. Sandberg (Reg. No. 41,287), Paul B. Simboli (Reg. No. 38,616), David L. Provence (Reg. No. 43,022), and Matthew W. Adams (Reg. No. 43,459) my attorneys and agents with full powers (including the powers of appointment, substitution, and revocation) to prosecute this application and any division, continuation, continuation-in-part, reexamination, or reissue thereof, and to transact all business in the Patent and Trademark Office connected therewith.

Please direct all correspondence in this case to:

Attention: Kevin W. Raasch
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Telephone No. (612) 305-1220
Facsimile No. (612) 305-1228

Declaration and Power of Attorney

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Serial No. Unassigned**Filing Date: December 20, 1999****Title: DEVICE FOR TAKING AND EXAMINING SAMPLES**

The undersigned declares further that all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Wherefore, I pray that Letters Patent be granted to me for the invention described and claimed in the specification identified above and I hereby subscribe my name to the foregoing specification and claims, Declaration and Power of Attorney, on the date indicated below.

1-00
Name Stefan Sauer

Citizenship: Germany

Post Office/Mailing Address: Spitzwegstrasse 13, D-82110 Germering, GERMANY DEX

December 13, 2000

Date

Declaration and Power of Attorney**Serial No. Unassigned****Filing Date: December 20, 1999****Title: DEVICE FOR TAKING AND EXAMINING SAMPLES**

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§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) Prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.